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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/643,384	08/19/2003	Kenneth Brasel	2836-H	4836
23373	7590	10/06/2006	EXAMINER	
SUGHRUE MION, PLLC 2100 PENNSYLVANIA AVENUE, N.W. SUITE 800 WASHINGTON, DC 20037			GAMBEL, PHILLIP	
			ART UNIT	PAPER NUMBER
			1644	

DATE MAILED: 10/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/643,384

Applicant(s)

BRASEL ET AL.

Examiner

Phillip Gambel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 July 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

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DETAILED ACTION

1. Applicant's amendment, filed 7/19/06, has been entered.
Claims 1, 9 and 15 have been amended.

Claims 1-23 are pending.

2. Applicant's election of the species bacteria in the Response to Election of Species Requirement, filed 7/19/06, is acknowledged.

Upon further consideration and search, the species has been extended to both bacterial and viral for examination purposes.

3. No Information Disclosure Statement has been filed in the instant application.

4. The filing date of the instant claims is deemed to be the filing date of instant USSN 10/643,384, filed 8/19/2003.

For example, it appears that the only support for the written description of "methods of treating infection in a patient having an infection" is the original claims of the instant application and not the instant specification, nor in the priority documents relied upon.

While the priority documents and the instant specification do disclose "the antigen may be one that already exists within the patient, such as a tumor antigen, or a bacterial or viral antigen" (e.g. see Summary of the Invention) or "flt3-L may be administered as a vaccine adjuvant ... for immunization purposes to enhance an immune response against tumor, viral or bacterial antigens" (e.g., see page 14, paragraph 2 of the instant specification),

Neither the instant specification nor the previous priority documents provide a sufficient written description for the broader genus of "treating an infection", broadly encompassed by the instant claims.

For example the reliance upon bacterial and viral antigens existing in patients or vaccines does not support broadening the disclosure of the priority documents to "treating infections", broadly encompassed by the instant claims.

Also, see MPEP 2163.05.

If applicant desires priority prior to 8/19/2003 for the instant claims, applicant is invited to point out and provide documentary support for the priority of the instant claims.

Applicant is reminded that such priority for the instant limitations requires written description and enablement under 35 U.S.C. § 112, first paragraph.

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Therefore, this application repeats a substantial portion of prior USSN 10/241,927, filed 9/11/2002 and adds and claims additional disclosure not presented in the prior application, as indicated above. Since this application names an inventor or inventors named in the prior application, it may constitute a continuation-in-part of the prior application. Should applicant desire to obtain the benefit of the filing date of the prior application, attention is directed to 35 U.S.C. 120 and 37 CFR 1.78.

Therefore, applicant should amend the first line of the specification to indicate the status of the instant application as a continuation-in-part.

A claim as a whole has only one effective filing date.

See Studiengesellschaft Kahle m.b.H. v. Shell Oil Co. 42 USPQ2d 1674, 1677 (Fed. Cir 1997).

5. The application is required to be reviewed and all spelling, TRADEMARKS, and like errors corrected.

Trademarks should be capitalized or accompanied by the ® or ™ symbol wherever they appear and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the trademarks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Appropriate corrections are required

6. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 C.F.R. § 1.75(d)(1) and M.P.E.P. § 608.01(I).

Correction of the following is required:

As indicated above with respect to priority and upon a review of the instant specification, it does not appear that the instant specification provides for antecedent basis for the recitation of "methods of treating infection in a patient having an infection" other than in the original claims of the instant application.

Again, this "limitation" is not readily apparent in the the instant specification, nor in the priority documents relied upon.

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Alternatively, applicant is invited to identify the written support for instant claims in the specification as filed (and as well as any USSN document relied upon for priority).

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. §102 that form the basis for the rejections under this section made in this Office Action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. Claims 1-23 are rejected under 35 U.S.C § 102(e) as being anticipated McKenna et al. (US 2004/0022760) (see entire document, particularly Summary of the Invention and Detailed Description of the Invention).

McKenna et al. teach the use of Flt3-ligand (e.g., see paragraphs [0054] – [0068]) in immunization protocols (e.g., see Therapeutic applications in paragraphs [0089] – [0159]), including its use as an adjuvant in vaccines comprising bacterial and viral antigens (e.g., see paragraphs [0078] –[0085], including Table 1 on pages 10-11 and paragraphs [0127] – [0129]) as well as known pharmaceutical compositions (e.g. see paragraphs [0085], [0092], [[0096] - [0120]) and modes of administration (e.g., see paragraphs [0121] –[0126] recited and encompassed by the claimed methods.

It does not appear that the claim language or limitations result in a manipulative difference in the method steps when compared to the prior art disclosure.

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10. Claims 1-23 are rejected under 35 U.S.C § 102(e) as being anticipated Rosenthal et al. (U.S. Patent No. 6,875,441) (see entire document, particularly Summary of the Invention and Detailed Description of the Invention).

Rosenthal et al. teach the use of Flt3-ligand (e.g., see Background of the Invention, column 7, paragraph 3 and Examples) in immunization protocols (e.g., see column 11, paragraph 6) including its use as an adjuvant in vaccines comprising bacterial and viral antigens (e.g., see column 11, paragraphs 6-7) as well as known pharmaceutical compositions and modes of administration (e.g., see columns 12-13) recited and encompassed by the claimed methods.

It does not appear that the claim language or limitations result in a manipulative difference in the method steps when compared to the prior art disclosure.

11. Claims 1-9, 11-15 and 17-23 are rejected under 35 U.S.C § 102(b) as being anticipated Lyman et al. (U.S. Patent No. 5,554,512) (see entire document, particularly Summary of the Invention and Detailed Description of the Invention).

Lyman et al. teach the use of Flt3-ligand (e.g., see columns 4-17 and Examples) [0068]) as well as known pharmaceutical compositions and modes of administration (e.g., see column 18, paragraphs 3-4) that can be use in methods to stimulate T cell proliferation as well hemopoietic cells in treating patients with HIV (e.g. see column 7, paragraph 3) encompassed by the claimed methods.

It does not appear that the claim language or limitations result in a manipulative difference in the method steps when compared to the prior art disclosure.

It is noted that even if applicant is able to obtain the earliest priority document relied upon, this reference would still stand as prior art under 35 USC 102(e).

12. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

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A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

13. Claims 1-23 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 11-12 of copending USSN 10/397,687.

The instant claims as well as the copending claims either anticipate or render obvious one another, given that both encompass the same or nearly the same methods of administering a composition or a vaccine comprising Flt3-ligand as an adjuvant to immunize a patient. Further, it is noted that copending claims 11-12 of USSN 10/397,687 refer to pending claims that also recite vaccines comprising bacterial and viral antigens and modes of administration which are consistent with the instant claims. The instant and copending claims anticipate or render obvious one another the instant claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

14. No claim is allowed.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (571) 272-0844. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841.

The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Phillip Gambel, Ph.D., J.D.
Primary Examiner
Technology Center 1600
September 30, 2006

A handwritten signature in black ink, appearing to read "Phillip Gambel", with a long horizontal flourish extending to the right.